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Remarks:

Regarding the rejection of claims 1-5 and 8 under 35 USC 103(a) as being unpatentable over WO 01/76371 to McKechnie et al. (hereinafter "McKechnie") in view of U.S. Patent No. 5,635,132 to Blanc:

Applicants respectfully traverse the rejection of the foregoing claims in view of McKechnie further in view of Blanc.

Prior to discussing the merits of the Examiner's position, the undersigned reminds the Examiner that the determination of obviousness under § 103(a) requires consideration of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368, 67 USPQ2d 1649, 1653 (Fed. Cir. 2003). There must be some suggestion, teaching, or motivation arising from what the prior art would have taught a person of ordinary skill in the field of the invention to make the proposed changes to the reference. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). But see also *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385 (U.S. 2007).

A methodology for the analysis of obviousness was set out in *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000) A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."

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It must also be shown that one having ordinary skill in the art would reasonably have expected any proposed changes to a prior art reference would have been successful. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

The Patent Office alleges that the combination of McKechnie and Blanc teaches or suggests each and every feature of claims 1-5 and 8. The Patent Office acknowledges that McKechnie only teaches using terpene in an amount of 5%. The Patent Office introduces Blanc as allegedly teaching that essential oils may be used in an amount up to 20% of the composition. Applicants disagree with these allegations.

The present application illustrates that allergen reduction depends on the physical form of the composition. Specifically, the present application shows that the inventive emulsions perform much better than oil-on-water compositions. The test samples of the present application shows there to be a significant increase in performance of an emulsion (91% allergen reduction) compared with oil-on-water (75.4% allergen reduction), at a like-for-like concentration of 12% (see paragraphs [0066]-[0074] of U.S. Patent Publication No. 2008/0226492 for the present application). Furthermore, increasing the deactivant loading to 20% or 50% did not produce any improvement. Applicants submit that the superior performance of the presently claimed emulsion is surprising and unexpected.

McKechnie does not teach or suggest increasing concentration of terpene to an amount greater than 5%. In contrast, the only emulsion examples in McKechnie are set forth in Example 3 and include lesser amounts of terpene. Specifically, the five test liquids of Example 3 include 2% tea tree oil, 2% citronella oil, 1% thymol, 2% hinoki oil and 2% tannic acid, respectively. Fig. 3 of McKechnie shows that the average allergen reduction

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for the five test liquids is about 37-70% for tea tree, citronella, thymol and hinoki oil and 99.1% for tannic acid (however tannic acid causes staining and is not usable in most situations). Other examples of McKechnie use impregnated candles, oil burners having deactivant floated on water, or a nebulizer. Example 1 of McKechnie describes similar components to those of Example 3 but the compositions are oil-on-water instead of emulsions. As seen in Fig. 1 of McKechnie, no significant overall advantage is seen for the emulsion samples (shown in Fig. 3) when compared to the oil-on-water samples (shown in Fig. 1).

Nowhere does McKechnie distinguish between the results of the emulsions and the oil-on-water compositions because the emulsions and oil-on-water compositions have generally the same results. McKechnie does *not* provide a skilled artisan with motivation to prepare emulsions of higher concentration. Moreover, McKechnie does not provide a skilled artisan with motivation to expect superior results for emulsions having a higher concentration of deactivant. Thus, to achieve the present invention, Applicants looked beyond the teachings expressed in McKechnie and surprisingly and unexpectedly found a beneficial result for emulsions having a higher concentration of deactivant.

McKechnie teaches that a volatile oil may be used in the form of an emulsion comprising up to 5% by weight of the oil (see page 4, lines 30-33 of McKechnie). In contrast, Blanc teaches a process for decontamination and detoxification of a room with a true aerosol diffused from the center of the room, whereby the true aerosol contains up to 20% essential oils and aromatic essences. Applicants also submit that one of ordinary skill in the art would not modify emulsions according to McKechnie with teaching direct to true aerosols according to Blanc because McKechnie's emulsion systems are such a different type of system compared to Blanc's true aerosol systems. Even if one of ordinary skill in the art did modify McKechnie with Blanc, as alleged by the Patent Office, the resulting combination would fail to achieve the presently claimed invention because neither McKechnie nor Blanc teach or suggest an oil-in-water emulsion having a deactivant in an amount greater 5% weight.

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In the Office Action, the Patent Office also alleges that it would have been obvious to increase the amount of terpene-containing essential oil in the oil-in-water emulsion of McKechnie where the level of dust mite allergens was very large as Blanc evidences the safety of using essential oils at high concentrations. To further support this rejection, the Patent Office alleges that concentration is a known result effective variable and it is within the purview of one in the art to optimize the concentration of the essential oil in McKechnie as being a result effective variable. Applicants respectfully disagree with these allegations by the Patent Office.

MPEP 2144.05(II)(B) sets forth:

A particular parameter must *first be recognized* as a result-effective variable, i.e., a variable which achieves a recognized result, *before the* determination of the optimum or workable ranges of said variable might be *characterized as routine experimentation*. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized *was not recognized in the art* to be a result-effective variable.). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy). (Emphasis added)

As acknowledged by the Patent Office, McKechnie teaches an oil-in-water emulsion which includes terpene in an amount of up to 5% by weight of the oil (see page 4, lines 30-33). Example 3 of McKechnie illustrates example emulsions having much lower amounts of terpene than 5% (see Fig. 3 and page 9, line 30 – page 10, line 29). As discussed above, the five test liquids of Example 3 include: 2% tea tree oil, 2% citronella oil, 1% thymol, 2% hinoki oil and 2% tannic acid, respectively. Fig. 3 of McKechnie illustrates that the % reduction of allergen in 0.1 g dust sample for each of the five test liquids of Example 3. The data in Fig. 3 shows that % reduction of allergen is not dependent upon the concentration of the terpene present in the samples as much as dependent upon the specific terpene used in the samples. For example, use of only 1%

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thymol caused a 57.8% reduction of allergen while use of 2% hinoki oil only caused a 37.4% reduction of allergen and use of 2% tannic acid caused a 99.1% reduction of allergen. Thus, at best, McKechnie shows that the % reduction of allergen is a direct result of the specific terpene used in the test liquids and *not* the amount or concentration of terpene.

Additionally, Blanc does not provide evidence that the % reduction of allergen is dependent upon the amount or concentration of essential oils and aromatic essences. At best, Blanc teaches a product having about 20% essential oils and aromatic essences (see col. 3, lines 57-61).

Accordingly, Applicants submit that there is no evidence of record that the concentration of terpene is a known result effective variable as alleged by the Patent Office. Therefore, the concentration of terpene is not recognized as a result-effective variable and determination of optimum concentration of the essential oil can not be characterized as obvious in view of the teachings of McKechnie and Blanc.

The fact that Applicants discovered an optimum concentration for the deactivant to achieve the present methods is not obvious. Accordingly, Applicants submit that a *prima facie* case of obviousness cannot be established and respectfully request that this rejection be withdrawn.

Moreover, McKechnie and Blanc, taken singly or in combination, fail to teach or suggest a method comprising dispersing into an airspace an allergen-deactivating amount of an allergen-deactivating compound, the compound being provided in the form of an oil-in-water emulsion comprising at least 8% weight of a deactivant, the emulsion being dispersed into the airspace as a vapour as required by amended claim 1. Furthermore, McKechnie and Blanc, taken singly or in combination, fails to teach or suggest a method comprising providing an oil-in-water emulsion, an allergen deactivant present in a

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concentration of 10-15% wt./wt. of emulsion, and heating the emulsion with a heat source to accelerate the vaporization of the deactivant as recited in claim 8.

Because these features of independent claims 1 and 8 are not taught or suggested by McKechnie and Blanc, taken singly or in combination, these references would not have rendered the features of claims 1 and 8 obvious to one of ordinary skill in the art.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

Regarding the rejection of claims 6 and 10 under 35 USC 103(a) as being unpatentable over McKechnie and Blanc in view of WO 03/070286 to Franklin et al. (hereinafter "Franklin"):

Applicants respectfully traverse the rejection of the foregoing claims in view of McKechnie, Blanc and Franklin.

The Patent Office acknowledges that McKechnie and Blanc do not teach or suggest use of β -pinene as the deactivant (see page 4 of the Office Action). The Patent Office introduces Franklin as allegedly teaching a composition containing water, a surfactant and pinene as a terpene. The Patent Office alleges that it would have been obvious to use pinene as the terpene of McKechnie since Franklin has evidenced its effectiveness against a variety of airborne contaminants, including dust mite allergens. Applicants respectfully disagree with the allegations by the Patent Office.

Franklin fails to remedy the deficiencies of McKechnie and Blanc as set forth above with respect to claims 1 and 8, from which claims 6 and 10, respectively, depend, because Franklin does not teach or suggest (a) an oil-in-water emulsion comprising at least 8% weight of a deactivant as required by claim 1 and (b) a step of providing an oil-in-water

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emulsion wherein an allergen deactivant is present in a concentration of 10-15% wt./wt. of emulsion as recited in claim 8.

Thus, McKechnie, Blanc and Franklin, taken singly or in combination, fail to teach or suggest a method comprising dispersing into an airspace an allergen-deactivating amount of an allergen-deactivating compound, the compound being provided in the form of an oil-in-water emulsion comprising at least 8% weight of a deactivant, the emulsion being dispersed into the airspace as a vapour as recited in claim 1, from which claim 6 depends. Moreover, McKechnie, Blanc and Franklin, taken singly or in combination, do not teach or suggest a method of deactivating an allergen at a locus having the step of providing an oil-in-water emulsion wherein an allergen deactivant is present in a concentration of 10-15% wt./wt. of emulsion as recited in claim 8.

Because the features of independent claims 1 and 8 are not taught or suggested by McKechnie, Blanc and Franklin, taken singly or in combination, these references would not have rendered the features of claim 6 and 10, respectively, obvious to one of ordinary skill in the art.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

Regarding the rejection of claim 7 under 35 USC 103(a) as being unpatentable over McKechnie and Blanc in view of U.S. Patent No. 6,500,445 to Pullen:

Applicants respectfully traverse the rejection of the foregoing claim in view of McKechnie, Blanc and Pullen.

The Patent Office acknowledges that McKechnie and Blanc do not teach or suggest use of orange oil as the deactivant (see page 4 of the Office Action). The Patent Office introduces Pullen as allegedly teaching a composition containing orange oil as a terpene-

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containing essential oil. The Patent Office alleges that it would have been obvious to use orange oil as the terpene-containing essential oil of McKechnie since Pullen teaches that terpene-containing essential oils such as orange oil are effective, non-toxic pesticides for dust mites. Applicants respectfully disagree with the allegations by the Patent Office.

Pullen fails to remedy the deficiencies of McKechnie and Blanc as set forth above with respect to claim 1, from which claim 7 depends, because Pullen does not teach or suggest an oil-in-water emulsion comprising at least 8% weight of a deactivant as required by claim 1.

Thus, McKechnie, Blanc and Pullen, taken singly or in combination, fail to teach or suggest a method comprising dispersing into an airspace an allergen-deactivating amount of an allergen-deactivating compound, the compound being provided in the form of an oil-in-water emulsion comprising at least 8% weight of a deactivant, the emulsion being dispersed into the airspace as a vapour as recited in claim 1, from which claim 7 depends.

Because these features of independent claims 1 are not taught or suggested by McKechnie, Blanc and Pullen, taken singly or in combination, these references would not have rendered the features of claim 7 obvious to one of ordinary skill in the art.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

Regarding the rejection of claims 9 and 11 under 35 USC 103(a) as being unpatentable over U.S. Patent Publication No. 2002/0022043 to Miller in view of Franklin:

Applicants respectfully traverse the rejection of the foregoing claims in view of Miller and Franklin.

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The Patent Office acknowledges that Miller fails to teach or suggest an oil-in-water emulsion. The Patent Office introduces Franklin as allegedly teaching an oil-in-water emulsion for control of dust mite allergens within a space. The Patent Office alleges that it would be obvious to one of ordinary skill in the art to employ the essential oil of Miller in the form of an oil-in-water emulsion in order to facilitate use of the essential oil while avoid waste. Applicants respectfully disagree with the allegations by the Patent Office.

Miller and Franklin, taken singly or in combination, do not teach or suggest allergen deactivating oil-in-water emulsion comprising at least 8% weight of a volatile deactivant wherein the deactivant is selected from oil of jasmine, oil of bergamot, oil of lemon grass, or a component thereof as required by claim 9.

Applicants submit that a *prima facie* case of obviousness cannot be established because the skilled artisan would not be motivated to apply the teachings of Franklin to modify Miller to achieve the presently claimed invention. Though Applicants do not concede that a combination of Miller and Franklin teaches all of the limitations of the presently claimed invention, even if such was the case, the skilled artisan would not be motivated to combine these teachings.

Miller teaches use of aromatherapy-grade oils produced by steam distillation of the specific plant whereby the oils release vapors spontaneously. Miller teaches that drops of the oil are placed adjacent to a substrate, are sprayed onto the substrate, are sprayed onto a impermeable barrier for covering the substrate or use of a packet containing a solution/gel of the oil (see the Abstract and paragraph [0011]).

Franklin teaches a composition for improving air quality, disinfecting surfaces, and prevention of a respiratory infection wherein the composition can be an emulsion of terpene. Example 3 of Franklin teaches an emulsion obtainable from lipids, emulsifier and terpene.

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Both the present claims and Franklin are directed to emulsion. Miller, on the other hand, is directed to oils themselves and solutions or gels including the oils. There is no teaching or suggestion in Miller or in its combination with Franklin that would motivate one of ordinary skill in the art to employ the essential oil of Miller in the form of an oil-in-water emulsion in order to facilitate use of the essential oil while avoiding waste as alleged by the Patent Office. Absent such teaching or suggestion in Miller or in its combination with Franklin, persons ordinarily skilled in the art would not have had a motivation to modify Franklin with the teachings of Miller as alleged by the Patent Office.

Based on the foregoing, Applicants submit that a *prima facie* case of obviousness has not been established, and respectfully request that the Patent Office withdraw this rejection.

Regarding the rejection of claims 12 and 13 under 35 USC 103(a) as being unpatentable over McKechnie in view of Blanc and further in view of Franklin:

Applicants respectfully traverse the rejection of the foregoing claims in view of McKechnie further in view of Blanc and Franklin.

As discussed above with respect to McKechnie and Blanc and claim 1, Applicants submit that there is no evidence of record that the concentration of terpene is a known result effective variable as alleged by the Patent Office. Franklin also fails to teach or suggest that the concentration of terpene is a known result effective variable. Therefore, the concentration of terpene is not recognized as a result-effective variable and determination of optimum concentration of the essential oil can not be characterized as obvious in view of the teachings of McKechnie and Blanc.

The fact that Applicants discovered an optimum concentration for the deactivant to achieve the present methods is not obvious. Accordingly, Applicants submit that a *prima*

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facie case of obviousness cannot be established and respectfully request that this rejection be withdrawn.

Moreover, McKechnie, Blanc and Franklin, taken singly or in combination, fail to teach or suggest a method of deactivating an allergen from the mite species Der f1 or Der p1, wherein the allergen-deactivating compound being provided in the form of an oil-in-water emulsion comprising at least 8% weight of a deactivant, wherein the oil-in-water emulsion being dispersed into the airspace as a vapour, wherein the oil-in-water emulsion comprises a non-ionic surfactant as an essential constituent of the oil-in-water emulsion as recited in claim 12.

Should the Examiner in charge of this application believe that telephonic communication with the undersigned would meaningfully advance the prosecution of this application, they are invited to call the undersigned at their earliest convenience.

The early issuance of a *Notice of Allowability* is solicited.

CONDITIONAL AUTHORIZATION FOR FEES

Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

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Respectfully Submitted;

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